

08/473789



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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/473,789	06/07/95	CURTISS	R MEGAN-100-21

EXAMINER

18M1/1223

RYAN, V	
ART UNIT	PAPER NUMBER

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1802

DATE MAILED: 12/23/97

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

- Responsive to communication(s) filed on September 18, 1997
- This action is FINAL.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- Claim(s) 1 - 38 is/are pending in the application.
Of the above, claim(s) 5-7, 15, 17-19, 21-22, 25, 26, 30-36 is/are withdrawn from consideration.
- Claim(s) _____ is/are allowed.
- Claim(s) 1-4, 8-14, 16, 20, 23, 24, 27-29, 37 is/are rejected.
- Claim(s) _____ is/are objected to.
- Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- The drawing(s) filed on _____ is/are objected to by the Examiner.
- The proposed drawing correction, filed on _____ is approved disapproved.
- The specification is objected to by the Examiner.
- The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- All Some* None of the CERTIFIED copies of the priority documents have been
- received.
 - received in Application No. (Series Code/Serial Number) _____.
 - received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- Notice of Reference Cited, PTO-892
- Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- Interview Summary, PTO-413
- Notice of Draftsperson's Patent Drawing Review, PTO-948
- Notice of Informal Patent Application, PTO-152

-SEE OFFICE ACTION ON THE FOLLOWING PAGES--

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DETAILED ACTION

The Examiner acknowledges receipt of the Amendment filed September 18, 1997.

The text of those sections of U.S. Code not included in this Office Action can be found in a prior Office Action.

In this application:

Claims 1-4, 8-14, 16, 20, 23, 24, 27-29, and 37 are now under examination.

This application contains claims 5-7, 13-15, 17-19, 21, 22, 25, 26, 30-36 drawn to an invention non-elected with traverse in Paper No. 9. A complete response to the final rejection must include cancellation of non-elected claims or other appropriate action (37 CFR 1.144) MPEP § 821.01.

Response to Amendment

- (1) The rejection of claims 1-4, 8-14, 16, 20, 23, 24, 27-29, and 37 under 35 U.S.C. 112, first paragraph is maintained.

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(2) The rejection of claims 1-3, 10-13, 16, 20, 23, 24, 27, 28, and 37 under 35 U.S.C. 102(b) as being anticipated by Gerdés et al (Proc. Natl Acad. Sci) is maintained.

(3) The rejection of claims 1-4, 10-12, 23, 24, and 27-29 under 35 U.S.C. 102(b) as being anticipated by Curtiss is withdrawn in view of Applicant's arguments.

(4) The rejection of claims 1-3, 8, 10-14, 16, 20, 27, 28, and 37 under 35 U.S.C. 102(b) as being anticipated by Gerdés et al (EMBO Journal) is maintained.

(5) The rejection of claims 1, 4, 10-14, 20, 23, 24, 27, and 37 under 35 U.S.C. 102(b) as being anticipated by Ramos et al is withdrawn in view of Applicant's arguments.

Applicant's arguments filed September 18, 1997 have been fully and carefully considered and they are not deemed to be persuasive regarding those rejections which are maintained.

(a) In response to the rejection of claims 1-4, 8-14, 16, 20, 23, 24, 27-29, and 37 under 35 U.S.C. 112, first paragraph, Applicant submits that the object of the claimed Environmentally Limited

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Viability System is not attenuated bacterial strains, but environmental control of bacterial strains, whether they are attenuated or not. Applicant also submits that the essential gene recited in the claims is expressed in the permissive environment (e.g. inside an animal in the case of a vaccine), and so does not contribute to any attenuating effect.

However, it is the Examiner's position that, since the bacterial strains are not attenuated, it would appear that virulent strains of bacteria (such as *Salmonella*) would be administered as a vaccine composition.

(b) In response to the rejection of claims 1-3, 10-13, 16, 20, 23, 24, 27, 28, and 37 under 35 U.S.C. 102(b) as being anticipated by Gerdes et al, Applicant submits that Gerdes et al disclose *E. coli* containing a *hok* gene linked to lambda PR which is regulated by the temperature-sensitive lambda CI857 repressor. Applicant also submits that the *hok* gene is a lethal gene which is expressed only when the temperature is raised to 42 C and the lambda CI857 repressor is inactivated, and expression of the *hok* gene produces a highly toxic gene product which causes rapid cell death. Applicant asserts that Gerdes et al, however, fail to disclose any environmentally regulated essential gene. Applicant

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further asserts that, since the claimed cells require both an environmentally regulated lethal gene and an environmentally regulated essential gene, Gerdes et al fail to disclose each and every feature of the claimed cells.

However, it is the Examiner's position that Gerdes et al disclose that the sok gene suppresses killing by encoding a product which counteracts the hok gene-mediated killing by interfering with a vital function in the cell membrane. Therefore, the sok gene is considered "essential" to the viability of the cell. In addition, the sok gene is not expressed at 30 degrees (non-permissive environment), and is activated at 42 degrees (permissive environment). Furthermore, the hok gene is not expressed at 42 degrees since the sok gene suppresses the hok gene at 42 degrees.

(d) In response to the rejection of claims 1-3, 8, 10-14, 16, 20, 27, 28, and 37 under 35 U.S.C. 102(b) as being anticipated by Gerdes et al (EMBO Journal), Applicant submits that Gerdes disclose E. coli containing a hok gene linked to lambda PR which is regulated by the temperature sensitive lambda CI857 repressor. Applicant also submits that the hok gene is expressed only when the temperature is raised to 42 degrees and the lambda IC857

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repressor is inactivated. Applicant, however, asserts that Gerdes et al fail to disclose an environmentally regulated lethal gene and an environmentally regulated essential gene.

However, it is the Examiner's position that Gerdes et al disclose that the sok gene suppresses killing by encoding a product which counteracts the hok gene-mediated killing by interfering with a vital function in the cell membrane. (See Abstract). Therefore, the sok gene is considered "essential" to the viability of the cell. In addition, the sok gene is not expressed at 30 degrees (non-permissive environment), and is activated at 42 degrees (permissive environment). (See especially page 3119). Furthermore, the hok gene is not expressed at 42 degrees since the sok gene suppresses the hok gene at 42 degrees.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened

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statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

The Art Unit location of your application in the Patent and Trademark Office has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1802.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to V. Ryan whose telephone number is (703) 305-6558.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to the Group 1800 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The fax number for Art Unit 1802 is (703) 308-4242.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [james.housel@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

V. Ryan
Patent Examiner/Art Unit 1802
December 1997
Ryan/vr

Mazel F. Sidberry
MAZEL F. SIDBERRY
PRIMARY EXAMINER
GROUP 1800